

Message

From: Weiner, Matthew [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=32B24B7FD1BF4C95B3404CBE8F467561-WEINER, MAT]
Sent: 3/5/2021 1:44:10 PM
To: Nathan Rose [nathan.rose@oxitec.com]; Bohnenblust, Eric [Bohnenblust.Eric@epa.gov]; Matthews, Keith [KMatthews@wiley.law]
CC: Kevin Gorman [Kevin.Gorman@oxitec.com]
Subject: RE: EUP amendment

Hi Nathan,

Yes I will. Feel free to forward it on to anybody I have missed.

Thanks!

Matt Weiner | Risk Manager | Emerging Technologies Branch | Biopesticides and Pollution Prevention Division (7511P)
Telework Number: (571) 398-5640
U.S. Environmental Protection Agency | 1200 Pennsylvania Ave. NW | Washington, D.C. 20460-0001

From: Nathan Rose <nathan.rose@oxitec.com>
Sent: Friday, March 5, 2021 8:22 AM
To: Weiner, Matthew <weiner.matthew@epa.gov>; Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>; Matthews, Keith <KMatthews@wiley.law>
Cc: Kevin Gorman <Kevin.Gorman@oxitec.com>
Subject: RE: EUP amendment

Hi Matt
That time works well for us – will you send a Teams invite?
Kind regards
Nathan

From: Weiner, Matthew <weiner.matthew@epa.gov>
Sent: 05 March 2021 14:13
To: Nathan Rose <nathan.rose@oxitec.com>; Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>; Matthews, Keith <KMatthews@wiley.law>
Cc: Kevin Gorman <Kevin.Gorman@oxitec.com>
Subject: RE: EUP amendment

Hi Nathan,

I totally understand. We don't have availability Thursday or Friday, but would you all be able to do Monday the 15th at 10am EST?

Thanks,

Matt Weiner | Risk Manager | Emerging Technologies Branch | Biopesticides and Pollution Prevention Division (7511P)
Telework Number: (571) 398-5640
U.S. Environmental Protection Agency | 1200 Pennsylvania Ave. NW | Washington, D.C. 20460-0001

From: Nathan Rose <nathan.rose@oxitec.com>
Sent: Friday, March 5, 2021 4:12 AM
To: Weiner, Matthew <weiner.matthew@epa.gov>; Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>; Matthews, Keith

<KMatthews@wiley.law>

Cc: Kevin Gorman <Kevin.Gorman@oxitec.com>

Subject: RE: EUP amendment

Hi Matt

Thanks for the quick reply, and look forward to meeting you!

My colleague Kevin and I are based in Europe, so I'm wondering whether the team might have a slot in the mornings EST later next week, e.g. Thurs or Fri?

Kind regards

Nathan

From: Weiner, Matthew <weiner.matthew@epa.gov>

Sent: 04 March 2021 22:22

To: Nathan Rose <nathan.rose@oxitec.com>; Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>; Matthews, Keith <KMatthews@wiley.law>

Cc: Kevin Gorman <Kevin.Gorman@oxitec.com>

Subject: RE: EUP amendment

Hi Nathan,

I am pleased to meet you. I think a call to make introductions and get orientated is an excellent idea. The soonest we are available to talk would be on Wednesday March 10 at 4:00pm EST. If that works for you and the rest of the team, please let me know and I can send a MS Teams invite around. I'm looking forward to talking with everybody.

Best,

Matt Weiner | Risk Manager | Emerging Technologies Branch | Biopesticides and Pollution Prevention Division (7511P)
Telework Number: (571) 398-5640
U.S. Environmental Protection Agency | 1200 Pennsylvania Ave. NW | Washington, D.C. 20460-0001

From: Nathan Rose <nathan.rose@oxitec.com>

Sent: Thursday, March 4, 2021 5:06 AM

To: Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>; Matthews, Keith <KMatthews@wiley.law>

Cc: Kevin Gorman <Kevin.Gorman@oxitec.com>; Weiner, Matthew <weiner.matthew@epa.gov>

Subject: RE: EUP amendment

Hi Matt

Just making contact on behalf of Oxitec – it would be great to have a brief call with you sometime to make introductions, and to update you on our current EUP project status, the amendment currently under review, and also the upcoming amendment we'll be submitting, to extend releases to the western USA. If you have some time for a call in the next week, let us know.

Kind regards

Nathan Rose

Nathan Rose, DPhil
Head of Regulatory Affairs
Oxitec Ltd
71 Innovation Drive, Milton Park
OX14 4RQ, UK
+44 (0) 1865 959 883
www.oxitec.com



From: Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>

Sent: 03 March 2021 16:19

To: Nathan Rose <nathan.rose@oxitec.com>; Matthews, Keith <KMatthews@wiley.law>

Cc: Kevin Gorman <Kevin.Gorman@oxitec.com>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>; Reynolds, Alan <Reynolds.Alan@epa.gov>; Weiner, Matthew <weiner.matthew@epa.gov>

Subject: RE: EUP amendment

Hi Keith, Nathan and Kevin,

Our review is coming along and we hope to be done in the next few weeks. I am not aware of any issues at this point, but we will let you know if anything comes up.

Also, I want to update you that I am moving to a new position with EPA on March 14 and will no longer be the contact for this action at that time. Matt Weiner, who I've cc'd will be taking over managing the action. Please cc him on future correspondence.

Thanks.

Eric Bohnenblust, Ph.D

Senior Biologist

Emerging Technologies Branch (ETB)

Biopesticides and Pollution Prevention Division (BPPD)

Phone: 703-347-0426

Email: Bohnenblust.eric@epa.gov

From: Nathan Rose <nathan.rose@oxitec.com>

Sent: Tuesday, March 2, 2021 10:25 AM

To: Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>; Matthews, Keith <KMatthews@wiley.law>

Cc: Kevin Gorman <Kevin.Gorman@oxitec.com>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>; Reynolds, Alan <Reynolds.Alan@epa.gov>

Subject: RE: EUP amendment

Hi Eric, Mike and Alan

Just checking in on these minor protocol amendments – we are targeting our first releases next month, so we will be relying on having these amendments finalised before then. If there's any further information you need, please let us know – we are always available for a quick call if helpful.

Kind regards

Nathan

From: Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>

Sent: 16 February 2021 14:56

To: Nathan Rose <nathan.rose@oxitec.com>; Matthews, Keith <KMatthews@wiley.law>

Cc: Kevin Gorman <Kevin.Gorman@oxitec.com>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>; Reynolds, Alan <Reynolds.Alan@epa.gov>

Subject: RE: EUP amendment

Hi Keith and Nathan,

We will need a stand-alone clean pdf label because we will need to stamp the revised label. You can send that through email directly to me. As far as the reviews, we have completed the section G review and the review of the other MRIDs is in progress.

Thanks.

Eric Bohnenblust, Ph.D
Senior Biologist
Emerging Technologies Branch (ETB)
Biopesticides and Pollution Prevention Division (BPPD)
Phone: 703-347-0426
Email: Bohnenblust.eric@epa.gov

From: Nathan Rose <nathan.rose@oxitec.com>

Sent: Monday, February 15, 2021 11:10 AM

To: Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>; Matthews, Keith <KMatthews@wiley.law>

Cc: Kevin Gorman <Kevin.Gorman@oxitec.com>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>; Reynolds, Alan <Reynolds.Alan@epa.gov>

Subject: RE: EUP amendment

Hi Eric and team

Hope you are all well!

Just checking in on the EUP amendment – do you have everything you need, and could you provide a brief progress update on the reviews? If this is easier done on a brief call, let us know.

Kind regards

Nathan

From: Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>

Sent: 27 January 2021 17:35

To: Nathan Rose <nathan.rose@oxitec.com>; Matthews, Keith <KMatthews@wiley.law>

Cc: Kevin Gorman <Kevin.Gorman@oxitec.com>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>; Reynolds, Alan <Reynolds.Alan@epa.gov>

Subject: RE: EUP amendment

Nathan,

They should be submitted as courtesy copies for reviewers, so they should not get new MRID numbers. I would describe what they are in the cover letter and clearly indicate that these are courtesy copies and not new studies and reference the already existing EUP amendment application.

Thanks.

Eric Bohnenblust, Ph.D
Senior Biologist
Emerging Technologies Branch (ETB)
Biopesticides and Pollution Prevention Division (BPPD)
Phone: 703-347-0426
Email: Bohnenblust.eric@epa.gov

From: Nathan Rose <nathan.rose@oxitec.com>

Sent: Wednesday, January 27, 2021 11:29 AM

To: Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>; Matthews, Keith <KMatthews@wiley.law>

Cc: Kevin Gorman <Kevin.Gorman@oxitec.com>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>; Reynolds, Alan <Reynolds.Alan@epa.gov>

Subject: RE: EUP amendment

Hi Eric

That's not a problem. Should these have new MRID numbers, or can we use the same MRIDs used when we submitted these in Dec?

Kind regards

Nathan

From: Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>

Sent: 27 January 2021 17:27

To: Nathan Rose <nathan.rose@oxitec.com>; Matthews, Keith <KMatthews@wiley.law>

Cc: Kevin Gorman <Kevin.Gorman@oxitec.com>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>; Reynolds, Alan <Reynolds.Alan@epa.gov>

Subject: RE: EUP amendment

Hi Keith and Nathan,

We have one request related to the pending EUP amendment. Could you please submit redline copies of the section G and revised MRIDs. I know there is a table in the one MRID which lists the changes but our reviewers would like to be able to see the changes easier throughout the document.

Thanks.

Eric Bohnenblust, Ph.D

Senior Biologist

Emerging Technologies Branch (ETB)

Biopesticides and Pollution Prevention Division (BPPD)

Phone: 703-347-0426

Email: Bohnenblust.eric@epa.gov

From: Nathan Rose <nathan.rose@oxitec.com>

Sent: Wednesday, January 20, 2021 8:59 AM

To: Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>

Cc: Matthews, Keith <KMatthews@wiley.law>; Kevin Gorman <Kevin.Gorman@oxitec.com>

Subject: EUP amendment

Dear Mike and Eric

Hope that you are both well!

Just wanted to check on the status of the review of the EUP protocol amendments, and whether it would be helpful to arrange a call to discuss any of the minor amendments requested.

Kind regards

Nathan

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